# NIGHTTIME COUGH RELIEF- dextromethorphan hydrobromide and doxylamine succinate liquid Rite Aid Corporation

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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# Rite Aid Corporation Nighttime Cough Relief Drug Facts

### Active ingredients (in each 30 mL dose cup)

Dextromethorphan HBr 30 mg

Doxylamine succinate 12.5 mg

### Purpose

Cough suppressant

Antihistamine

#### Uses

temporarily relieves cold symptoms

- cough
- runny nose and sneezing

#### **Warnings**

#### Do not use

- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- to make a child sleepy

# Ask a doctor before use if you have

- glaucoma
- cough that occurs with too much phlegm (mucus)
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough as occurs with smoking, asthma, or emphysema
- trouble urinating due to an enlarged prostate gland

# Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers

# When using this product

- do not use more than directed
- excitability may occur, especially in children
- may cause marked drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness

# Stop use and ask a doctor if

• cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.

# If pregnant or breast-feeding,

ask a health professional before use.

#### Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

#### **Directions**

- take only as directed
- use dose cup
- do not exceed 4 doses per 24 hrs

adults & children 12 yrs & over	30 mL (2 TBSP) every 6 hrs
children 4 to under 12 yrs	ask a doctor
children under 4 yrs	do not use

 when using other Daytime or Nighttime products, carefully read each label to insure correct dosing

#### Other information

- each 30 mL dose cup contains: sodium 32 mg
- store at 20°-25°C (68°-77°F)

# **Inactive ingredients**

alcohol, anhydrous citric acid, FD&C blue no. 1, FD&C red no. 40, flavor, high fructose corn syrup, polyethylene glycol, propylene glycol, purified water, saccharin sodium, sodium citrate

#### Questions or comments?

1-800-719-9260

#### **Principal Display Panel**

Compare to the active ingredients in Vick's® NyQuil® Cough

nighttime cough relief cough (dextromethorphan HBr) sneezing, runny nose (doxylamine succinate) cough suppressant antihistamine cherry flavor all night cough relief 10% ALCOHOL



Purpose

Antihistamine

#### NIGHTTIME COUGH RELIEF

dextromethorphan hbr, doxylamine succinate liquid

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:11822-0668
Route of Administration	ORAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>DEXTRO METHO RPHAN HYDRO BRO MIDE</b> (DEXTRO METHO RPHAN)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg in 30 mL	
DO XYLAMINE SUCCINATE (DO XYLAMINE)	DOXYLAMINE SUCCINATE	12.5 mg in 30 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ALCOHOL		
ANHYDRO US CITRIC ACID		
FD&C BLUE NO. 1		
FD&C RED NO. 40		
HIGH FRUCTO SE CORN SYRUP		
POLYETHYLENE GLYCOLS		
PROPYLENE GLYCOL		
WATER		
SACCHARIN SO DIUM DIHYDRATE		
SODIUM CITRATE		

Product Characteristics		
Color	RED (Dark Red)	Score
Shape		Size
Flavor	CHERRY	Imprint Code
Contains		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0668-1	237 mL in 1 BOTTLE		
2	NDC:11822-0668-2	355 mL in 1 BOTTLE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/07/2002	

# Labeler - Rite Aid Corporation (014578892)

Revised: 10/2012 Rite Aid Corporation